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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 09/913,970  | 03/28/2002  | Alexander Fred Markham | 9052-87             | 8326             |
| 20792   | 7590        | 03/19/2004             | EXAMINER            |                  |
| MYERS BIGEL SIBLEY & SAJOVEC<br>PO BOX 37428<br>RALEIGH, NC 27627 |             |                        | SULLIVAN, DANIEL M  |                  |
|   |             |                        | ART UNIT            | PAPER NUMBER     |
|   |             |                        | 1636                |                  |

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

**Application No.**

09/913,970

**Applicant(s)**

MARKHAM ET AL.

**Examiner**

Daniel M Sullivan

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,7,9,11,12,14 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4,7,9,11,12,14 and 25-46 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 7 and 28-30, drawn to an isolated nucleic acid encoding a latency promoter comprising a nucleic acid sequence homologous to or capable of hybridizing with SEQ ID NO: 1.

Group II, claim(s) 25 and 31, drawn to a method of treating a disorder in a subject comprising administering a nucleic acid according to Group I.

Group III, claim(s) 26, 27, 32 and 33, drawn to a pharmaceutical composition comprising the nucleic acid of Group I.

Group IV, claim(s) 9, 11, 12 and 34-36, drawn to a gene therapy system comprising a vector encoding a latency promoter comprising a nucleic acid sequence homologous to or capable of hybridizing with SEQ ID NO: 1.

Group V, claim(s) 37, drawn to a method of treating a disorder in a subject comprising administering to a subject the gene therapy system of Group IV.

Group VI, claim(s) 38 and 39, drawn to a pharmaceutical composition comprising the gene therapy system of Group IV.

Group VII, claim(s) 14 and 40-43, drawn to an HVS comprising a nucleic acid encoding a latency promoter comprising a nucleic acid sequence homologous to or capable of hybridizing with SEQ ID NO: 1.

Group VIII, claim(s) 44, drawn to a method of treating a disorder in a subject comprising administering the HVS of Group VII.

Group IX, claim(s) 45 and 46, drawn to a pharmaceutical composition comprising the HVS of Group VII.

Art Unit: 1636

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. In the instant case, the shared technical feature appears to be the latency promoter having a sequence homologous to the sequence set forth as SEQ ID NO: 1. However, as pointed out in the International Preliminary Examination Report for PCT/GB00/00537, Nicholas *et al.* (1992) *Nature* 355:362-365 (made of record in the IDS filed 17 August 2001) teaches a nucleic acid sequence comprising the complementary sequence of SEQ ID NO: 1. As the sequence set forth as SEQ ID NO: 1 would be obvious to one of ordinary skill in the art based on the complementary sequence taught by Nicholas *et al.*, the shared technical feature that links the inventions lacks an inventive step according to PCT Article 33(3). Therefore, the shared technical feature is not a contribution over the prior art.

The special technical feature of Group I is the isolated nucleic acid encoding a latency promoter comprising a nucleic acid sequence homologous to or capable of hybridizing with SEQ ID NO: 1.

The special technical feature of Group II is a method of treating a disorder in a subject comprising administering a nucleic acid.

The special technical feature of Group III is a pharmaceutical composition comprising a nucleic acid.

The special technical feature of Group IV is a gene therapy system comprising a vector encoding a latency promoter comprising a nucleic acid sequence homologous to the nucleic acid sequence set forth as SEQ ID NO: 1.

The special technical feature of Group V is a method of treating a disorder in a subject comprising administering to a subject a gene therapy system.

The special technical feature of Group VI is a pharmaceutical composition comprising a gene therapy system.

The special technical feature of Group VII is an HVS comprising a nucleic acid encoding a latency promoter comprising a nucleic acid sequence homologous to or capable of hybridizing with SEQ ID NO: 1.

The special technical feature of Group VIII is method of treating a disorder in a subject comprising administering an HVS.

The special technical feature of Group IX is a pharmaceutical composition comprising an HVS.

Accordingly, Groups I-IX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
DAVID GUZO  
PRIMARY EXAMINER